

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

TRUTEK CORP.,

Plaintiff,

v.

Case No. 2:21-cv-10312

BLUEWILLOW BIOLOGICS, INC.;
ROBIN ROE 1 through 10, gender
neutral fictitious names, and; ABC
CORPORATION 1 through 10 (fictitious
names).

Hon. Stephen J. Murphy, III
Mag. R. Steven Whalen

Defendants.

**DEFENDANT/COUNTER-PLAINTIFF BLUEWILLOW
BIOLOGICS, INC.'S OPPOSITION TO PLAINTIFF'S MOTION TO
DISMISS DEFENDANT'S COUNTERCLAIMS**

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STATEMENT OF ISSUE PRESENTED

1. Whether this Court should deny Plaintiff/Counter-Defendant's motion to dismiss as Defendants/Counter-Plaintiff's Counterclaims adequately plead facts sufficient to support counterclaims for non-infringement and invalidity of the patent in dispute.

Plaintiff/Counter-Defendant's answer: **No.**

Defendant/Counter-Plaintiff's answer: **Yes.**

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I. INTRODUCTION

This is a classic nuisance patent lawsuit in which Trutek Corp. (“Truetek”) is seeking to extort a large settlement from a product with minimal sales by leveraging the cost of defending against the lawsuit. BlueWillow Biologics, Inc. (“BlueWillow”) filed Counterclaims seeking declaratory judgments that: (i) BlueWillow did not infringe Trutek’s patent; and (ii) Trutek’s patent is invalid.

Trutek’s instant Motion to Dismiss BlueWillow’s Counterclaims is without merit and must be denied. Notably, Trutek’s Motion relies entirely on generalized statements regarding pleading and fails to cite even a single case concerning the pleading requirements for non-infringement or invalidity counterclaims, let alone any cases demonstrating that it is entitled to the relief it now seeks at the pleading stage.¹

Trutek’s Motion should be denied. Even a cursory review of case law regarding the pleading standards for patent non-infringement and invalidity counterclaims would have alerted Trutek that its Motion is without merit.

¹ Aside from citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 554, 570 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) for general pleading standards, Trutek only cites two cases, *L.M. Sessler* and *Microsoft*, neither of which are relevant for the reasons explained herein.

II. BACKGROUND

BlueWillow is a clinical-stage biopharmaceutical company focused on developing a new generation of safe and effective intranasal vaccines for challenging respiratory infections, sexually transmitted diseases, and food allergies. (Dkt. 9, Counterclaim, ¶ 6). BlueWillow developed and sold NanoBio® Protect², an over-the-counter nasal antiseptic that uses BlueWillow's proprietary nanotechnology to deliver benzalkonium chloride (BZK), a common skin antiseptic that has been used in over-the-counter products for more than 75 years. (*Id.* ¶ 7).

On February 10, 2021, Trutek filed suit alleging one count of patent infringement of United States Patent No. 8,163,802 ("the '802 Patent") against BlueWillow with respect to a single product, NanoBio® Protect. (Dkt. 9, Counterclaim ¶ 6; Dkt. 1, Complaint). The '802 Patent is attached as Exhibit 6 to the Complaint. (Dkt. 1-6.) Trutek's Complaint alleges that BlueWillow's NanoBio® Protect directly infringes "at least claims 1, 2, and 7 of the ['802] Patent because the [NanoBio® Protect] products possess an electrostatic charge when

² BlueWillow has put Trutek on notice of the fact that sales of NanoBio® Protect (the only accused product at issue) are extremely limited, spanning a period of a little over one year and having ceased as of May 2021. Thus, the amount in controversy does not justify further litigation, let alone the increased cost of baseless motion practice at the pleadings stage.

applied to a person’s nasal passages, and they use benzalkonium chloride as a biocide.” (Dkt. 9, Counterclaim, ¶ 9; Dkt. 1, Complaint, ¶ 30.)

On May 19, 2021, BlueWillow filed its responsive pleading, including its Counterclaims. (Dkt. 9). Consistent with its denial of Trutek’s allegations, Count I of BlueWillow’s Counterclaims seeks a declaratory judgment that BlueWillow has not infringed the ’802 Patent. Count II of BlueWillow’s Counterclaims seeks a declaratory judgment that the ’802 Patent is invalid. Specifically, BlueWillow alleges that “[a]ll claims of the ’802 Patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and 112.” (*Id.* ¶ 19). BlueWillow further identifies specific prior art references that render the ’802 Patent invalid – “[f]or example, at least the following prior art references render each claim of the ’802 Patent invalid under 35 U.S.C. § 102 and/or § 103: U.S. Patent No. 6,559,189; U.S. Patent No. 6,506,803; U.S. Patent No. 10,138,279; U.S. Published Application No. 2006/0163149; U.S. Published Application No. 2004/0071757; and U.S. Patent No. 5,468,488.” (*Id.* ¶ 20).

III. STANDARD OF REVIEW

A. Motion to Dismiss

Federal Rule of Civil Procedure 8(a)(2) requires a complaint to include “a short and plain statement of the claim showing that the pleader is entitled to relief.” *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 512 (2002) (unanimous). This

simplified notice pleading standard applies to all civil actions, subject to limited exceptions (not applicable here). *Id.* at 513 (citing Fed. R. Civ. P. 9(b)). The liberal notice pleading of Rule 8(a) is the starting point of a simplified pleading system, which was adopted to focus litigation on the merits of a claim.” *Id.* at 514. Rule 8(a) does “not require heightened fact pleading or specifics, but only enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 562–63 (2007). Notably, the Court has unequivocally rejected a “punctiliously stated ‘theory of the pleadings,’” explaining that the Federal Rules “effectively abolish the restrictive theory of the pleading doctrine, making it clear that it is unnecessary to set out a legal theory for the plaintiff’s claim for relief[.]” *Johnson v. City of Shelby*, 574 U.S. 10, 12 (2014) (per curiam).

IV. ARGUMENT

A. **Trutek’s Motion Should be Denied on its Face as it Fails to Develop an Articulable, Developed, and Substantiated Argument**

The Court should reject Trutek’s Motion on its face as it fails to cite any case law regarding the requirements for pleading non-infringement or invalidity counterclaims and fails to provide even a cursory, let alone well-supported, explanation of why the asserted deficiencies warrant dismissal at this stage. For example, while Trutek cites *L.M. Sessler Excavating & Wrecking, Inc. v. Bette & Cring, LLC*, No. 16-CV-06534, 2017 WL 4652709 (W.D.N.Y. Oct. 17, 2017) in the “Legal Standard” section of its Motion, this case relates to pleading

requirements for a cause of action for a patent infringement claim—*not* a counterclaim for non-infringement or invalidity. Trutek does not explain why *L.M. Sessler* supports the proposition that BlueWillow’s counterclaims for non-infringement and invalidity are insufficiently well-pled under *Twombly/Iqbal*.

Indeed, as is the case with Trutek’s Motion, “issues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived. It is not sufficient for a party to mention a possible argument in the most skeletal way, leaving the court to put flesh on its bones.” *McPherson v. Kelsey*, 125 F.3d 989, 995–96 (6th Cir. 1997); *see also White Oak Prop. Dev., LLC v. Washington Twp.*, 606 F.3d 842, 850 (6th Cir. 2010) (“perfunctory” and “nebulous” argument renders an issue forfeited). Nevertheless, as explained in more detail below, Trutek’s Motion should also be denied on the merits.

B. BlueWillow Adequately Pled its Declaratory Judgment Counterclaim of Non-infringement (Count I)

BlueWillow adequately pled factual matter sufficient to plead a counterclaim for non-infringement. In the context of pleading non-infringement, there are only two facts that must be pled:³ (1) the existence of the patent, and (2) the non-

³ There are additional requirements for a declaratory judgment action, neither of which are at issue in Trutek’s Motion. *Pfizer, Inc. v. Apotex, Inc.*, 726 F. Supp. 2d 921, 928–29 (N.D. Ill. 2010) (stating that a declaratory judgment action requires (1) an actual case and controversy that is (2) of sufficient “immediacy and reality” to be justiciable under Article III of the U.S. Constitution).

infringement of the patent. *Cf. Evolve Techs., LLC v. Coil Winding Specialist, Inc.*, Case No. 3:18-cv-00671BEN-BGS, 2019 WL 1383272, at *2 (S.D. Cal. Mar. 27, 2019) (“general denials of infringement [are] sufficient to sustain declaratory judgment claims for patent non-infringement at the pleading stage”). Both are present here. BlueWillow pled the following in support of its non-infringement counterclaim:

13. BlueWillow has not and does not, either literally or under the doctrine of equivalents, directly or indirectly infringe any valid and enforceable claim of the '802 Patent. For example, NanoBio® Protect does not restrict the flow of airborne contaminants or particulate matter into nasal passages and/or hold such airborne contaminants or particulate matter outside the body, does not inactivate particulate matter, and does not prevent infection by electrostatically inhibiting harmful particulate matter, as required by the '802 Patent claims.

(Dkt. # 9, ¶ 13.) While admittedly “a short and plain statement,” which is permitted under Rule 8(a)(2), this is unquestionably sufficient under *Iqbal* and *Twombly* as well and Trutek’s Motion should be denied.

As an initial matter, it is not necessary that a counterclaimant explain “why” it does not infringe as that is a legal theory—which is not required to be pled. *Johnson*, 574 U.S. at 12; *Hand Held Prods., Inc. v. Code Corp.*, No. 17-167-RMG, 2017 WL 2537235, at *3 (D.S.C. June 9, 2017) (in the context of a patent invalidity counterclaim, holding that “[f]ailure to provide the legal basis for a claim [] is not a basis for a motion to dismiss.”). Indeed, courts have determined that

non-infringement counterclaims with even less detail were sufficiently well pled. *See, e.g., Finalrod IP, LLC v. Endurance Sols., Inc.*, Case No. 2:20-cv-00189-JRG-RSP, 2020 WL 7222803, at *2 (E.D. Tex. Oct. 30, 2020); *CryoLife, Inc. v. C.R. Bard, Inc.*, No. 14-559-SLR, 2015 WL 1069397, at *4 (D. Del. Mar. 10, 2015); *Pfizer, Inc. v. Apotex, Inc.*, 726 F. Supp. 2d 921, 937 (N.D. Ill. 2010); *Elan Pharma Int’l Ltd. v. Lupin Ltd.*, No. 09-1008 (JAG), 2010 WL 1372316, at *4 (D.N.J. March 31, 2010) (concluding that non-infringement counterclaims merely averring that the defendant’s product did not infringe the asserted patents satisfied Rule 8(a) and put plaintiff on notice of defendant’s claims of non-infringement).

Moreover, BlueWillow’s non-infringement counterclaim does not merely make “a broad unsubstantiated statement that it does not infringe,” as Trutek incorrectly suggests in the single paragraph of argument it presents in its Motion. Dkt. #11 at 7. Rather, BlueWillow pled specific facts regarding the operation of NanoBio® Protect, which plausibly demonstrate on their face that NanoBio® Protect does not meet one or more elements of the asserted claims.⁴ *Cf. Evolve*,

⁴ The burden of proof on infringement is on the patent owner, even in an action for declaratory judgment. *See Pfizer*, 726 F. Supp. 2d at 937. “In order for a court to find infringement, the plaintiff must show the presence of every element or its substantial equivalent in the accused device.” *DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1322 (Fed. Cir. 2001). In other words, the accused product does not infringe if it does not practice one or more limitations of the claims. *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1539 (Fed. Cir. 1991) (“[F]ailure to meet a single limitation is sufficient to negate infringement of the claim.”).

2019 WL 1383272, at *2 (stating that a counterclaimant need not “set forth every permutation of its non-infringement theories on an element-by-element basis.”).

Trutek identifies claims 1, 2, and 7 of the '802 Patent in its Complaint.

(Dkt. # 1, ¶ 30.) Independent claim 1 states the following:

1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:

- a) electrostatically attracting the particulate matter to the thin film;
- b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
- c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

(Dkt. # 1-6, PgID 44.) Claims 2 and 7 contain similar limitations.

BlueWillow pled facts that plausibly support its assertion that NanoBio®

Protect does not practice one or more limitations of the asserted patent claims.

Compare Wahpeton, 870 F.2d at 1552 n.9 *with Twombly*, 550 U.S. at 562–63.

Moreover, “[o]ne who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.” *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989).

More specifically, BlueWillow pled facts that, if true, would mean that NanoBio® Protect does not satisfy the preamble of the asserted claims (should the preamble be found limiting upon claim construction), or any of limitations a) through c). Indeed, elementary logic dictates that a product that is alleged to “not inactivate particulate matter” cannot satisfy a claim limitation that requires “inactivating the particulate matter.” (Compare Dkt. # 9, ¶ 13 with Dkt. # 1-6, PgID 44.) Likewise, the allegations that NanoBio® Protect “does not restrict the flow of airborne contaminants or particulate matter into nasal passages and/or hold such airborne contaminants or particulate matter outside the body” and “does not prevent infection by electrostatically inhibiting harmful particulate matter” present a claim that is plausible on its face that the product does not meet the remaining limitations of the asserted claims. *Id.*

Courts have found that significantly less satisfies the pleading requirements. For example, in *Finalrod*, the Eastern District of Texas held that the following allegations were sufficient to state a counterclaim of non-infringement:

11. Finalrod has asserted that Endurance's S300 directly and/or indirectly, either literally or under the doctrine of equivalents, infringes the '625 Patent and has done so since April 25, 2020.

12. Endurance's S300 has not infringed and does not infringe, either directly or indirectly, any valid and enforceable claim of the '625 patent; it is not the case that the each and every limitation of Claims 13-15 of the

'625 patent are present directly and/or indirectly, either literally or under the doctrine of equivalents, in the S300.

2020 WL 7222803, at *2. Not only did BlueWillow plead analogous facts as those in *Finalrod*, BlueWillow also pled (although not required) specific aspects of the accused product that are outside the scope of the '802 Patent claims. (*Compare* Dkt. # 9, ¶ 13 and Dkt. # 1-6, PgID 44.) Additionally, as noted in *Finalrod*, Defendant's counterclaims were "of course, in response to [the] complaint and, thus, implicitly includes the facts provided in [the] complaint." *Finalrod*, 2020 WL 7222803, at *2 n. 1. In other words, BlueWillow's counterclaim for non-infringement should only be dismissed if Trutek's Complaint is also dismissed. *O'Lear v. Miller*, 222 F. Supp. 2d 862, 863 (E.D. Mich. 2002) ("The Court has the power to dismiss a complaint *sua sponte* pursuant to Rule 12(b)(6)")

Similarly, in *CryoLife*, the District of Delaware found the following was sufficient to state a counterclaim of non-infringement:

The use, offer for sale, and/or sale of CryoLife's PerClot products has not infringed, does not infringe, and would not, when marketed and sold, directly or indirectly infringe any valid claim of the '461 patent, either literally or under the doctrine of equivalents, when CryoLife's PerClot products are used in a manner consistent with that set forth in the Proposed Instructions for Use (IFU). More particularly, the use of CryoLife's PerClot products has not infringed, does not infringe, and would not infringe, directly or indirectly, any valid claim of the '461 patent, either literally or under the doctrine of equivalents, because CryoLife's PerClot products behave

in use like the prior art which was argued by the patentee to be fundamentally different during prosecution.

2015 WL 1069397, at *4. BlueWillow pled significantly more facts than the well-pled allegation in *CryoLife*, which abstractly referred to a category of “behavior” that is noninfringing. Here, BlueWillow identified specific aspects of the accused product that bring it outside of the asserted claims.

As BlueWillow properly pled facts that, if true, would warrant a finding of non-infringement as to at least one limitation of the asserted claims, Trutek’s Motion should be denied. *See Evolve*, 2019 WL 1383272, at *2; *see also DeMarini Sports*, 239 F.3d at 1322; *Laitram*, 939 F.2d at 1539.

C. BlueWillow Adequately Pled its Declaratory Judgment Counterclaim of Invalidity (Count II)

BlueWillow adequately pled factual matter sufficient to plead a counterclaim for invalidity of the ’802 Patent. In its second count, BlueWillow pled:

19. All claims of the ’802 Patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and 112.

20. For example, at least the following prior art references render each claim of the ’802 Patent invalid under 35 U.S.C. § 102 and/or § 103: U.S. Patent No. 6,559,189; U.S. Patent No. 6,506,803; U.S. Patent No. 10,138,279; U.S. Published Application No. 2006/0163149; U.S. Published Application No. 2004/0071757; and U.S. Patent No. 5,468,488.

(Dkt. # 9, ¶¶ 19–20.)

Sections 35 U.S.C. §§ 101, 102, 103, and 112 are statutory requirements for

patent validity. With respect to patent invalidity counterclaims, courts have routinely held that alleging a patent is invalid for one or more statutory requirements is sufficient. *See, e.g., CryoLife*, 2015 WL 1069397, at *4; *Roland Corp. v. inMusicBrands, Inc.*, No. 16-cv-06256-CBM-AJWx, 2017 WL 3473928, at *2 (C.D. Cal. Apr. 5, 2017); *Pfizer*, 726 F. Supp. 2d at 937; *Elan Pharm.*, 2010 WL 1372316, at *4. Indeed, a patent is invalid unless it satisfies every statutory requirement for patentability. BlueWillow clearly pled facts that, if true, would render the patent invalid under one or more of these provisions.

For example, the question of whether a patent is indefinite under § 112 and thus invalid is purely a question of law. *See Infinity Comput. Prods. v. Oki Data Ams., Inc.*, 987 F.3d 1053, 1059 (Fed. Cir. 2021). Accordingly, the only fact needed to be pled under § 112 is a reference to the patent itself. As another example, under § 103, a patent claim is obvious (and thus invalid) if the “differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made” *Uniloc 2017 LLC v. Apple, Inc.*, 843 Fed. Appx. 305, 312 (Fed. Cir. 2021). Accordingly, a patent can be held invalid for obviousness based solely on the patent itself and the prior art. Both were pled and nothing more is required. *See Twombly*, 550 U.S. at 562–63.

Trutek separately asserts that multiple “grounds” or “theories” cannot be pled in a single “count.” As with its other arguments, Trutek fails to cite any case law in support of this assertion. Contrary to Trutek’s assertion, courts routinely find counterclaims that plead multiple “theories” of invalidity are well pled. *See, e.g., CryoLife*, 2015 WL 1069397, at *4; *Roland*, 2017 WL 3473928, at *2; *Pfizer*, 726 F. Supp. 2d at 937; *Elan Pharma*, 2010 WL 1372316, at *4. Indeed, *theories* are not required to be pled, *cf. Johnson*, 574 U.S. at 12, let alone in separate counts. Moreover, Rule 10(b) only requires claims “founded on separate transaction or occurrence” to be pleaded as a “separate count” when it would “promote clarity.” Here, invalidity of the ’802 Patent is neither a “separate transaction or occurrence” nor would it promote clarity to plead each theory for invalidity as a separate count.

Trutek’s remaining assertions lack merit as well. First, it is not necessary at the pleading stage to describe in detail every potential ground for invalidity. *See Teirstein v. AGA Med. Corp.*, No. 6:08cv14, 2009 WL 704138, at *5 (E.D. Tex. Mar. 16, 2009) (“Defendant [] specifically listed the statutory provisions that compel the asserted invalidity and noted that the ’995 patent fails to satisfy one of more of the statutory requirements,” which is “more than sufficient to give Plaintiff fair notice of what Defendant is claiming”—invalidity based on the “fail[ure] to satisfy one or more of the listed statutory provisions for patentability.”); *Boldstar Tech., LLC v. Home Depot, Inc.*, 517 F. Supp. 2d 1283, 1290 (S.D. Fla. 2007)

(holding that it was sufficient that the counterclaimant pled that the patent was invalid on “one or more” statutory grounds). As such, Trutek’s assertion that BlueWillow’s counterclaim needed to do more than identify the relevant statutory sections and exemplary prior art is not well founded.

Second, Trutek cites no support—whatsoever—for its assertion that rules governing patent examiners under MPEP § 706 applies to litigants at the pleading stage. To the contrary, the only pleading requirement for patent invalidity counterclaims is provided by Rule 8(a)’s liberal pleading standard, which does not require legal theories to be pled. *See Hand Held*, 2017 WL 2537235, at *2–3.

Third, Trutek’s reliance on *Microsoft* for the presumption of validity is misplaced, as that proposition is directed to the ultimate burden of proof and thus, is not relevant at the pleadings stage. *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91 (2001); *see also Teva Pharm. Indus., Ltd. v. Apotex*, No. 07-5514 (GEB)(JJH), 2008 WL 3413862 (D.N.J. Aug. 8, 2008) (declining to dismiss antitrust claim on basis of presumption of validity because the presumption “is an evidentiary burden that can be rebutted” and is not “controlling” at the motion to dismiss stage).

Finally, Trutek cites no authority for its assertion that BlueWillow must specifically identify which statutory section and/or prior art invalidates each claim on a claim-by-claim basis. *See Hand Held*, 2017 WL 2537235, at *3 (legal arguments are not required to be pled). BlueWillow adequately pled and identified

each of the statutory sections it contends invalidate the asserted claims, along with exemplary prior art references. Nothing more is required at the pleadings stage. *See Teirstein v. Aga Med. Corp.*, 2009 WL 704138, at *5.

Indeed, courts have held that invalidity contentions with significantly less satisfied *Twombly/Iqbal*. For example, the District Court for South Carolina held the following invalidity counterclaim was sufficiently well-pled:

254. On information and belief, each and every claim of the '258, '008, '223, '413, '128, and '472 patents is invalid for failure to comply with the conditions and requirements for patentability specified in, but not limited to, 35 U.S.C. §§ 101-103, 111-113, and 116 in effect at the time the patent issued.

Hand Held, 2017 WL 2537235, at *3

BlueWillow alleged significantly more, including by specifically identifying invalidating prior art. Nothing more is required. *See, e.g., CryoLife*, 2015 WL 1069397, at *4; *Roland*, 2017 WL 3473928, at *2; *Pfizer*, 726 F. Supp. 2d at 937; *Elan Pharma*, 2010 WL 1372316, at *4.

Accordingly, Trutek's Motion should be denied.

V. CONCLUSION

For the reasons stated herein, BlueWillow requests that the Court deny Trutek's Motion in its entirety. Should the Court decide that additional allegations are necessary, BlueWillow requests leave to file amended counterclaims following the Court's guidance.

Dated: June 25, 2021

Respectfully submitted,

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CERTIFICATE OF ELECTRONIC SERVICE

I hereby certify that on June 25, 2021, I electronically filed this document, **DEFENDANT/COUNTER-PLAINTIFF BLUEWILLOW BIOLOGICS, INC.'S OPPOSITION TO PLAINTIFF'S MOTION TO DISMISS DEFENDANT'S COUNTERCLAIMS**, with the Clerk of the Court for the Eastern District of Michigan using the ECF System.

/s/ Alan J. Gocha
Alan J. Gocha (P80972)